510(k) SUMMARY

K130267

As required by section 807.92

MAY 3 1 2013

Submitter	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 799 40 25 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.ch Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Trade Name	ROMEO posterior osteosynthesis system
SPECIAL 510k	ROMEO posterior osteosynthesis system – Line extension
CFR section	888.3070 and 888.3050
Classification Name	Pedicle screw spinal system / Spinal interlaminal fixation orthosis
Class	II
Product Codes	KWP Spinal interlaminal fixation orthosis MNH orthosis, spondylolisthesis spinal fixation MNI orthosis, spinal pedicle fixation
Device panel	ORTHOPEDIC
Legally marketed predicate devices	ELLIPSE posterior osteosynthesis system (K081165) and ROMEO posterior osteosynthesis system (K093170, K 101678, K111127 and K112108) manufactured by SPINEART
e-copy Statement	The eCopy is an exact duplicate of the paper copy

Description: The modifications to ROMEO posterior osteosynthesis system (K081165, K093170, K101678, K111127 and K112108) manufactured by SPINEART consist of:

- Addition of Romeo® 25D & 25T Screws made of Titanium alloy Ti6AI4V ELI conforming to ISO 5832.3 and ASTM F136
- Addition of Romeo® Straight and Multiaxial Cross Connectors made of Titanium alloy Ti6AI4V ELI conforming to ISO 5832-3 and ASTM F136
- Additional lengths of Percutaneous Pre-bent and Straight Rods made of Titanium alloy (Ti6AI4V ELI conforming to ISO 5832-3 and ASTM F136).

These components are supplied either sterile or not sterile.

- Addition of a Cross connector caliper and a 3.5 mm tightener (not sterile).

Intended Use ROMEO posterior osteosynthesis system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). When used as a posterior, non-cervical, non-pedicle screw fixation system, ROMEO posterior osteosynthesis system is intended for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Performance data ROMEO posterior osteosynthesis additional components conforms to special control established for Pedicle screw spinal system and to « Spinal System 510(k)s - Guidance for Industry and FDA Staff Document » issued on: May 3, 2004.
Mechanical testing including static compression bending, static torsion, dynamic axial compression tests have been performed according to ASTM F1717-12. Results demonstrate that additional components perform as safely and effectively as their predicate devices. No clinical data has been presented.

Substantial equivalence ROMEO posterior osteosynthesis system additional components are substantially equivalent to their predicate devices in terms of intended use, material, design, mechanical properties and function.
Non clinical performance testing according to special control and Verification Activity and Validation Activity demonstrate that additional components are as safe, as effective, and performs as safely and effectively as their predicate devices.

Preparation date, January 31th, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: May 31, 2013

SPINEART
% Mr. Franck Pennesi
Director of Industry & Quality
International Center Cointrin 20 route de pré-bois CP1813
1215 Geneva 15
Switzerland

Re: K130267
Trade/Device Name: ROMEO posterior osteosynthesis system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: February 22, 2013
Received: March 15, 2013

Dear Mr. Pennesi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130267

Device Name: ROMEO Posterior osteosynthesis system

Indications for Use:

ROMEO posterior osteosynthesis system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

When used as a posterior, non-cervical, non-pedicle screw fixation system, ROMEO posterior osteosynthesis system is intended for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130267